

AT/PTW

Docket: H-US-00497 (1544-3)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Roman Turovskiy et al. EXAMINER: Peter J. Vrettakos
SERIAL No.: 10/622,800 GROUP: 3739
FILED: July 18, 2003 DATED: April 25, 2007
TITLE: **DEVICE AND METHODS FOR COOLING
MICROWAVE ANTENNAS**

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Va. 22313-1450

TRANSMITTAL OF APPELLANTS' BRIEF

Sir:

Enclosed please find APPELLANTS' BRIEF.

Please charge the required fee under 37 C.F.R. § 41.20(b)(2) to Deposit Account No. **21-0550**. Also, in the event any additional extensions of time are required, please treat this paper as a petition to extend the time as required and charge Deposit Account No. **21-0550**. TWO (2) COPIES OF THIS SHEET ARE ENCLOSED.

Respectfully submitted,

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Dated: April 25, 2007

Nicole Rispone



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BRIEF ON APPEAL

Sir:

This is an appeal from a Final Office Action dated October 26, 2006 and an Advisory Action January 18, 2007 in the above-identified application. This Brief is accompanied by the requisite fees set forth in 37 C.F.R. §41.20 (b)(2).

I. REAL PARTY IN INTEREST

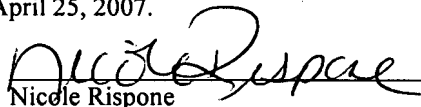
The real party in interest for this application is Sherwood Services AG.

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Nicole Rispone

II. RELATED APPEALS AND INTERFERENCES

Appellants' legal representative and/or the assignee of Appellants' interest in the above-identified application are not aware of any related appeals, interferences or judicial proceedings which may be related to, directly affect, or be directly affected by or have a bearing on any decision by the Board of Patent Appeals and Interferences in this appeal.

III. STATUS OF CLAIMS

The instant application was originally filed with seventy-seven (77) claims. Independent Claim 1 and dependent Claims 2-24 are pending in this application and are involved in this Appeal, Claims 25-78 have been previously withdrawn. Each of claims 1-24 stands finally rejected as set forth in the Final Office Action mailed October 26, 2006 (the "Final Office Action") and the Advisory Action mailed January 18, 2007. An accurate copy of Claims 1-24 is provided in the Claims Appendix.

IV. STATUS OF AMENDMENTS

The Advisory Action mailed January 18, 2007 indicates that the Response to the Final Office Action of October 26, 2006, filed on December 26, 2006 (referred to on the Advisory Action under "Request for Reconsideration/Other") has been considered but failed to place the application in condition for allowance.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent Claim 1 is directed to a cooling system for use with a microwave antenna. (Specification page 9, paragraph [0066]). The cooling system includes a

cooling jacket adapted to at least partially surround a microwave antenna. (Specification page 10, paragraph [0066]). The cooling jacket defines a fluid channel around at least a portion of the microwave antenna. (Specification page 11, paragraph [0069]). The cooling jacket is further adapted to circulate a cooling fluid through the fluid channel such that at least a portion of the microwave antenna is in direct fluid contact with the cooling fluid and wherein the microwave antenna comprises a distal tip configured to be advanced percutaneously through tissue. (Specification page 11, paragraph [0069]).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellants request review of the following outstanding grounds of rejection:

A) The rejection of Claims 1-16 and 19-24 under 35 U.S.C. §103(a) as being unpatentable over Storm (U.S. Patent 4,140,130) in view of Edwards (U.S. Patent 5,964,755) and further in view of Gough et al. (U.S. Patent 5,951,547) and even further in view of Rudie et al. (U.S. Patent 6,496,737);

B) The rejection of Claim 18 under 35 U.S.C. §103(a) as being unpatentable over Storm '130 in view of Edwards '755 and further in view of Gough et al. '547 and even further in view of Uthe (U.S. Patent 5,829,519) and further in view of Rudie et al. '737;

C) The rejection of Claim 17 under 35 U.S.C. §103(a) as being unpatentable over Storm '130 in view of Edwards '755 and further in view of Gough et al. '547 and even further in view of Edwards (U.S. Patent 5,281,217) and further in view of Rudie et

al. '737; and

D) The rejection of Claims 1-24 as being provisionally rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over Claims 25-45 and 64-77 of co-pending U.S. Application Serial No. 11/053,987.

VII. ARGUMENT

A) The rejection of Claims 1-16 and 19-24 under 35 U.S.C. §103(a) as being unpatentable over Storm (U.S. Patent 4,140,130) in view of Edwards (U.S. Patent 5,964,755) and further in view of Gough et al. (U.S. Patent 5,951,547) and even further in view of Rudie et al. (U.S. Patent 6,496,737)

Claims 1-16 and 19-24 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Storm (U.S. Patent 4,140,130) in view of Edwards (U.S. Patent 5,964,755) and further in view of Gough et al. (U.S. Patent 5,951,547) and even further in view of Rudie et al. (U.S. Patent 6,496,737).

Claim 1 of Appellants' disclosure recites a cooling system for use with a microwave antenna, including, *inter alia*, a cooling jacket adapted to at least partially surround a microwave antenna and defining a fluid channel around at least a portion of the microwave antenna, wherein the cooling jacket is further adapted to circulate a cooling fluid through the fluid channel such that at least a portion of the microwave antenna is in direct fluid contact with the cooling fluid and wherein the microwave antenna comprises a distal tip configured to be advanced percutaneously through tissue.

Appellants respectfully submit that Claim 1 is not obvious in view of Storm, Edwards, Gough and/or even in view of Rudie.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

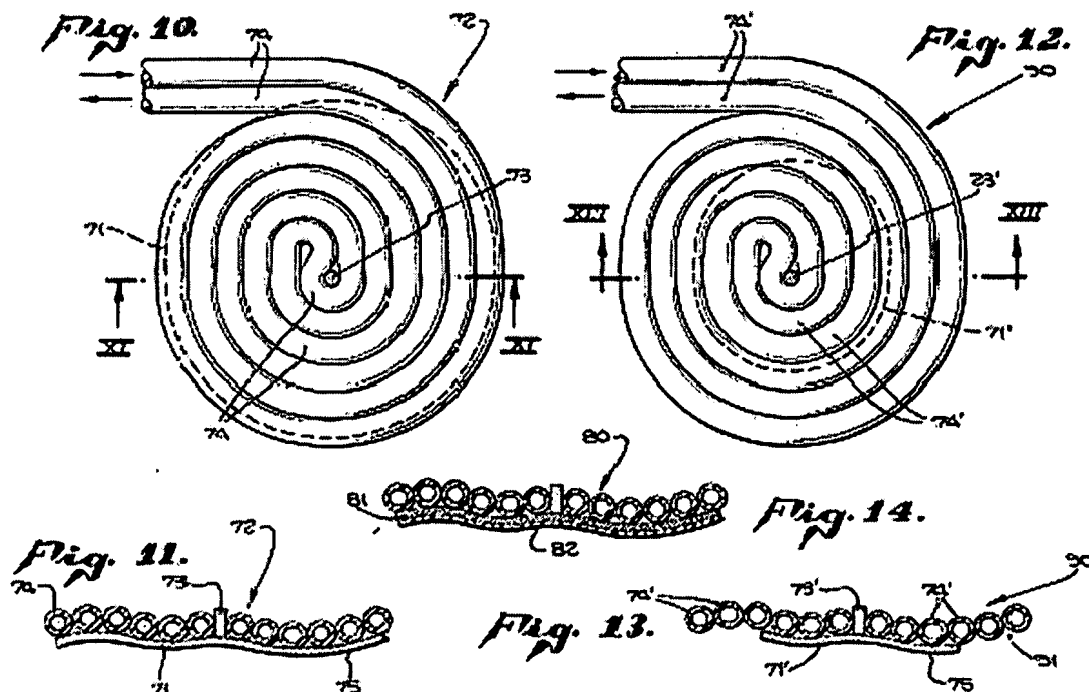
In addition, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or modification to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. "The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). See also *In re Lee*, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (discussing the importance of relying on objective evidence and making specific factual findings with respect to the motivation to combine references); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re*

Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

First, the Examiner has failed to shown how the prior art references teach or suggest all of the limitations of Appellants' Claim 1.

For example, in regards to Storm '130, Storm '130 fails to disclose that (1) at least a portion of the microwave antenna is in direct fluid contact with the cooling fluid; and (2) wherein the microwave antenna comprises a distal tip configured to be advanced percutaneously through tissue, as recited in Appellants' Claim 1.

Appellants submit that Storm '130 discloses, as shown in FIGS. 10-14 below, non-invasive electrode means 72 for electromagnetic radiational heating of tumor bearing tissue. The electrode means 72 is configured and adapted for placement on an outer surface of the tissue of the patient. (see, Storm '130, Col. 11, lines 38-43).



A cooling chamber means 74 is provided by a flexible tubing wound in spiral fashion about the post 73 and outwardly therefrom to cover the area of the metalized material 75 provided on the emitting surface 71. (see Storm '130, Col. 11, lines 50-54).

In the Final Rejection dated October 26, 2006, the Examiner concedes that "Storm '130 neglects to expressly mention a tissue penetrating microwave antenna." Appellants also submit that the Examiner should have taken notice or conceded that Storm '130 neglects to expressly mention or show that at least a portion of the microwave antenna is in direct fluid contact with the cooling fluid, as recited in Claim 1. In the Final Rejection dated October 26, 2006, the Examiner fails to indicate what features of Storm '130, if any, are being relied upon in establishing the rejection of Claims 1-16 and 19-24 under 35 U.S.C. §103(a).

In regards to Edwards '755, Edwards '755 fails to disclose the cooling system as recited in Appellants' Claim 1, when taken in any proper combination with Storm '130. In particular, Edwards '755 fails to disclose that (1) the cooling jacket is adapted to circulate a cooling fluid through the fluid channel such that the microwave antenna is in direct fluid contact with the cooling fluid; and (2) wherein the microwave antenna comprises a distal tip configured to be advanced percutaneously through tissue.

Appellants submit that Edwards '755 discloses, as shown in FIGS. 1C and 4 below, an ablation apparatus 10. The ablation apparatus 10 includes an expandable member 12 that is introduced into a desired body organ or lumen through an introducer sleeve 14. (see Edwards '755, Col. 4, lines 1 and 2).

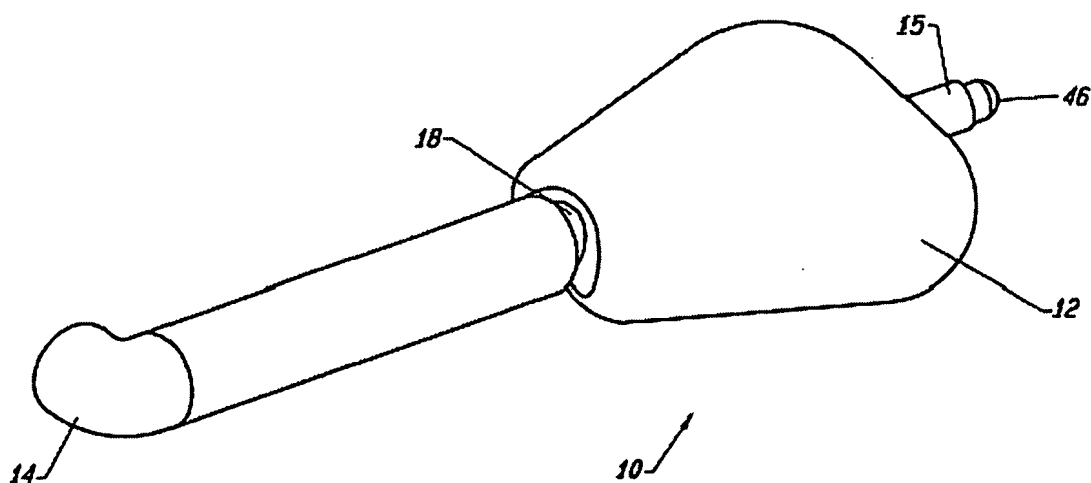


FIG. 1C

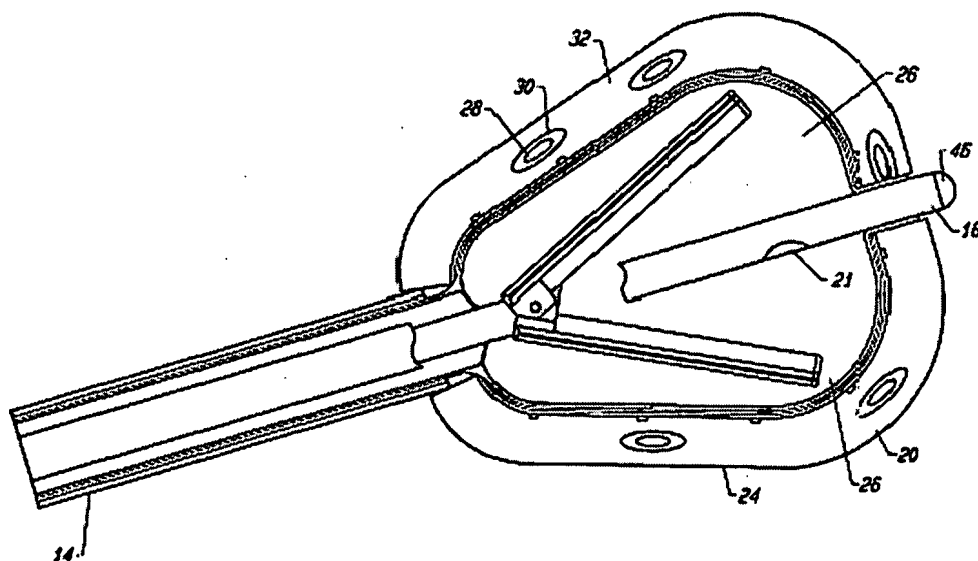


FIG. 4

Appellants submit that Edwards '755 teaches a heating of the fluid in or through the expandable member 12. According to Edwards '755, electrolytic solution in expandable member 12 is heated to a pre-selected temperature, which can be modified and adjusted as necessary. (see Edwards '755, Col. 5, lines 18-21) According to

Edwards '755, electrolytic solution can be heated and maintained at a temperature between about 60 to 90 degrees C. By providing a heated electrolytic solution, there is a reduction in the amount of time needed to complete a satisfactory ablation. (see Edwards '755, Col. 5, lines 21-27). Appellants thus submit that if the electrolytic solution is to be heated, then the electrolytic solution can not perform any cooling function, as called for in Claim 1.

Therefore, Edwards '755 does not disclose a cooling system for use with a microwave antenna and may not be properly combined with Storm '130 to render present Claim 1 obvious.

Appellants further respectfully submit that Edwards '755 fails to disclose a microwave antenna including a distal tip configured to be advanced percutaneously through tissue, as called for in Claim 1.

In the Final Rejection dated October 26, 2006, the Examiner takes the position that since introducer 14 is disclosed for use with a microwave antenna, that the ablation apparatus of Edwards '755 is "capable of tissue penetration." The Examiner also asserts that "tissue penetration includes entry into body lumens such as the cervix." Appellants respectfully submit that such an interpretation is clearly flawed.

Appellants respectfully submit that the introducer sleeve 14 of Edwards '755 is not a part of the microwave antenna, as the Examiner has concluded.

According to Edwards '755, the expandable member 12 is introduced through introducer sleeve 14. (see Edwards '755, Col. 4, lines 17-18). Introducer sleeve 14 is introduced into the desired organ or body lumen, as shown in FIG. 1(a) of Edwards '755 below, with expandable member 12 in a non-deployed configuration. (see Edwards '755, Col. 4, lines 32-34). According to Edwards '755, following introduction, introducer sleeve 14 is withdrawn and can be retracted into handle 16. (see Edwards '755, Col. 4, lines 34-36).

As such, in view of the foregoing, Appellants respectfully submit that introducer sleeve 14 of Edwards '755 is not a part or component of the microwave antenna and thus Edwards '755 fails to disclose a microwave antenna comprising a distal tip configured to be advanced percutaneously through tissue, as called for in Claim 1.

Appellants thus respectfully submit that Edwards '755 fails to remedy the deficiencies of Storm '130, and thus may not be taken in any proper combination with Storm '130 to teach or suggest all the limitations of independent Claim 1.

In regards to Gough '547, Gough '547 fails to disclose any cooling system and, more particularly, fails to disclose (1) the cooling jacket is adapted to circulate a cooling fluid through the fluid channel such that the microwave antenna is in direct fluid contact with the cooling fluid, recited in Appellants' Claim 1.

Appellants submit that Gough '547 discloses, as shown in FIG. 1 below, an ablation apparatus 10. The ablation apparatus 10 includes a multiple antenna device 12 having a primary antenna 14, and one or more secondary antennas 16, which are typically

electrodes. Secondary antennas 16 are positionable in a primary antenna lumen before or after advancement of primary antenna 14 through tissue. In use, when primary antenna 14 reaches a selected tissue ablation site secondary antennas 16 are laterally deployed from the primary antenna lumen and into the selected tissue mass.

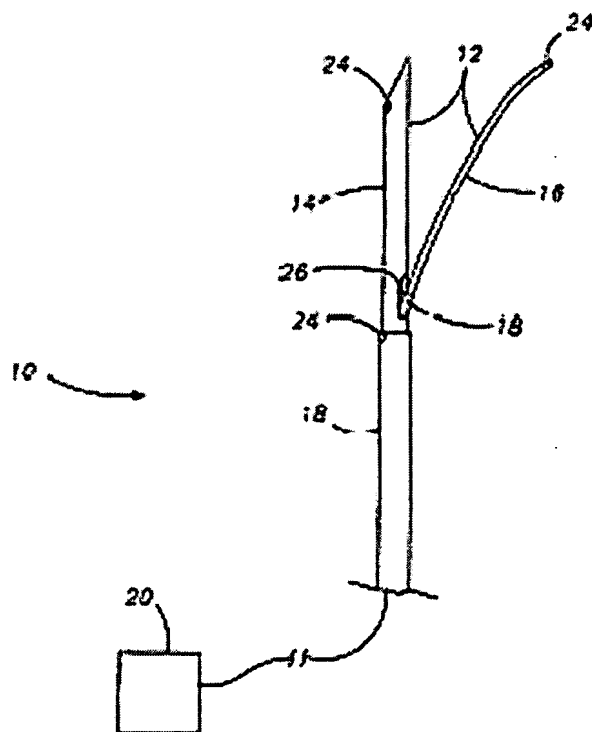


FIG. - 1

Appellants respectfully submit that Gough ‘547 fails to remedy the deficiencies of Storm ‘130 and Edwards ‘755 in that Gough ‘547 fails to disclose any form of cooling or of a cooling system, and thus may not be taken in any proper combination with Storm ‘130 in view of Edwards ‘755 to teach or suggest all the limitations of independent Claim 1.

In regards to Rudie '737, Appellants respectfully submit that Rudie '737 fails to disclose that (1) at least a portion of the microwave antenna is in direct fluid contact with the cooling fluid; and (2) wherein the microwave antenna comprises a distal tip configured to be advanced percutaneously through tissue.

Appellants submit that Rudie '737 discloses, as shown in FIGS. 2, 4A and 4B below, a thermal therapy catheter that contains a microwave antenna 57 held in place within an antenna lumen 70 in the catheter by heat shrink tubing 87. (see Col. 4, lines 64-67). Antenna lumen 70 is sealed at a distal end by plugs 70A and 70B, forming cavity 86 therebetween. (see Col. 4, lines 59-61.) Plugs 70A and 70B prevent fluid from entering the portion of the antenna lumen that contains the microwave antenna therefore the microwave antenna does not make direct fluid contact with the cooling fluid. In addition, heat shrink tubing 87 completely surrounds the microwave antenna 57 thereby forming a second layer that prevents direct contact between the microwave antenna and the cooling fluid.

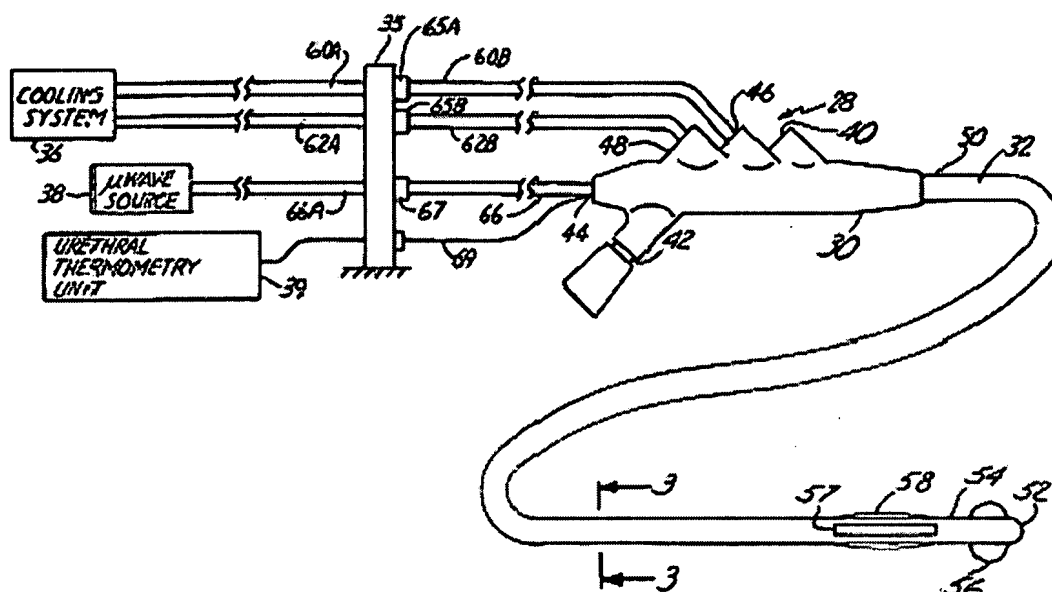
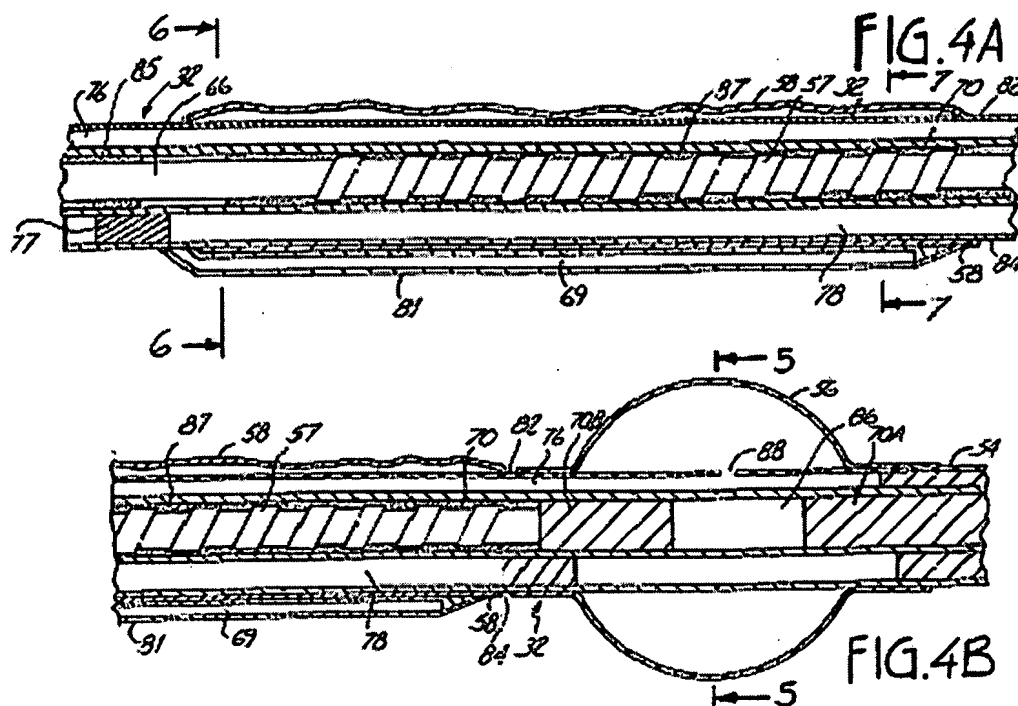


FIG. 2



In the Final Rejection dated October 26, 2006, the Examiner takes the position that Rudie '737 discloses "a microwave antenna (lumen 70) in direct connection (permitting a direct cooling effect on the antenna – motivation) with cooling fluid (fluid lumen 78-80) that is encapsulated by a cooling jacket (32)." Appellants respectfully submit that such an interpretation is clearly flawed.

As recited above, microwave antenna 57 of Rudie '737 is encapsulated by heat shrink tubing 87 and thus can not possibly allow for cooling fluid to directly contact the microwave antenna, as called for in Claim 1. Additionally, Rudie '737 is completely devoid of any teaching of a distal tip that is configured for percutaneous tissue advancement.

Appellants thus respectfully submit that Rudie '737 fails to remedy the deficiencies of Storm '130, Edwards '755 and Gough '547, and thus may not be taken in any proper combination with Storm '130 in view of Edwards '755 and further in view of Gough '547 to teach or suggest all the limitations of independent Claim 1.

Accordingly, the rejection of Claims 1-16 and 19-24 under 35 U.S.C. §103(a) as being unpatentable over Storm '130 in view of Edwards '755 and further in view of Gough '547 and even further in view of Rudie '737 has not been established because the Examiner has failed to shown how the prior art references, taken alone or in combination, teach or suggest all of the limitations of Appellants' Claim 1. Therefore, Appellants respectfully submit that a *prima facie* case of obviousness has not been established and the rejection of Claims 1-16 and 19-24 under 35 U.S.C. §103(a) should be reversed.

Second, in addition to the prior art references not teaching or suggesting all the claim limitations of Claim 1, the Examiner also has failed to establish a reasonable motivation to combine the prior art references in order to arrive at Appellants' Claim 1.

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). A statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). See also *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000).

If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). In addition, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

For example, Appellants respectfully submit that there would have been no motivation to modify Storm '130 with the teachings of Edwards '755, Gough '547 and/or Rudie '737, as suggested by the Examiner, to include the limitations lacking or missing therein.

As discussed above, Storm '130 discloses a non-evasive device configured and adapted for placement on the outer surface of the tissue of the patient to treat internal tissue. Appellants respectfully submit that this is not a situation where the mere substitution or addition of features to the disclosure of Storm '130, from the other cited references, would render Appellants' Claim 1 obvious. In contrast, the structure of Storm '130 would require a substantial reconstruction and redesign of the elements shown in Storm '130 as well as change the basic principle under which the Storm '130 construction was designed to operate, which is not sufficient to render Claim 1 *prima facie* obvious. (See M.P.E.P. § 2143.01(VI.)). Similar situations exist with the proposed combination of Edwards '755, Gough '547 and/or Rudie '737.

For this additional reason, the rejection of Claims 1-16 and 19-24 under 35 U.S.C. §103(a) as being unpatentable over Storm '130 in view of Edwards '755 and further in view of Gough '547 and even further in view of Rudie '737 has not been established because the Examiner has failed to a motivation to combine the prior art cited references. Accordingly, Appellants respectfully submit that the rejection of Claims 1-16 and 19-24 under 35 U.S.C. §103(a) should be reversed.

B) The rejection of Claim 18 under 35 U.S.C. §103(a) as being unpatentable over Storm '130 in view of Edwards '755 and further in view of Gough et al. '547 and even further in view of Uthe (U.S. Patent 5,829,519) and further in view of Rudie et al. '737

For at least the reasons presented above regarding the patentability of Claims 1-16 and 19-24 under 35 U.S.C. §103(a) as being unpatentable over Storm '130 in view of Edwards '755 and further in view of Gough '547 and even further in view of Rudie '737, Claim 18, which depends from Claim 1, is also patentably distinguishable over Storm '130 in view of Edwards '755 and further in view of Gough '547 and even further in view of Uthe '519 and further in view of Rudie '737.

C) The rejection of Claim 17 under 35 U.S.C. §103(a) as being unpatentable over Storm '130 in view of Edwards '755 and further in view of Gough et al. '547 and even further in view of Edwards (U.S. Patent 5,281,217) and further in view of Rudie et al. '737

For at least the reasons presented above regarding the patentability of Claims 1-16 and 19-24 under 35 U.S.C. §103(a) as being unpatentable over Storm '130 in view of Edwards '755 and further in view of Gough '547 and even further in view of Rudie '737, Claim 17, which depends from Claim 1, is also patentably distinguishable over Storm '130 in view of Edwards '755 and further in view of Gough '547 and even further in view of Edwards '217 and further in view of Rudie '737.

D) The rejection of Claims 1-24 as being provisionally rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 25-45 and 64-77 of co-pending U.S. Application Serial No. 11/053,987

Upon information and belief, the present application and Application Serial No. 11/053,987 are commonly owned. As such, upon the indication of allowability of the

Appl. No. 10/622,800

Brief on Appeal dated April 25, 2007

Reply to Final Office Action mailed October 26, 2006

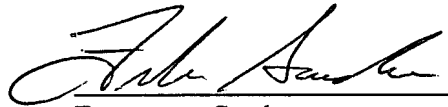
claims of the present application, except for the double patenting rejection, should the double patenting rejection remain following the present response, an appropriate terminal disclaimer will be submitted thereby obviating the rejection.

VIII. CONCLUSION

In view of the foregoing remarks, Appellants respectfully submit that all of the claims now pending in this application, namely, Claims 1-24 are in condition for allowance. Early and favorable reconsideration of this application is respectfully requested.

Please charge any deficiency as well as any other fee(s) which may become due under 37 C.F.R. §1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s) to Deposit Account No. 21-0550. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge Deposit Account No. 21-0550 therefor.

Respectfully submitted,



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IX. CLAIMS APPENDIX

1. A cooling system for use with a microwave antenna, comprising:
a cooling jacket adapted to at least partially surround a microwave antenna and defining a fluid channel around at least a portion of the microwave antenna,
wherein the cooling jacket is further adapted to circulate a cooling fluid through the fluid channel such that at least a portion of the microwave antenna is in direct fluid contact with the cooling fluid and wherein the microwave antenna comprises a distal tip configured to be advanced percutaneously through tissue.
2. The system of claim 1 further comprising at least one inlet lumen and at least one outlet lumen each in fluid communication with the cooling jacket for circulating the cooling fluid therethrough.
3. The system of claim 2 wherein a distal end of the inlet lumen is positioned near or at a distal end of the microwave antenna.
4. The system of claim 2 wherein a distal end of the outlet lumen is positioned proximally of the microwave antenna distal end.
5. The system of claim 2 wherein the inlet lumen is defined along an outer surface of the cooling jacket.

6. The system of claim 2 wherein the inlet lumen is defined within a wall of the cooling jacket.

7. The system of claim 1 further comprising a tip at a distal end of the cooling jacket.

8. The system of claim 7 wherein the tip is tapered.

9. The system of claim 7 further comprising a power generator in electrical communication with the tip.

10. The system of claim 7 wherein a distal end of the microwave antenna is securable to a proximal portion of the tip.

11. The system of claim 10 wherein the tip is adapted to be in electrical communication with the distal end of the microwave antenna.

12. The system of claim 1 further comprising a handle assembly for attachment to a proximal end of the cooling jacket.

13. The system of claim 12 wherein the handle assembly defines at least one lumen therethrough which is in fluid communication with the cooling jacket.

14. The system of claim 1 further comprising a pump for circulating the cooling fluid through the cooling jacket.

15. The system of claim 1 wherein the cooling fluid comprises a liquid, gas, or combination thereof.

16. The system of claim 15 wherein the liquid comprises water or saline.

17. The system of claim 15 wherein the gas is selected from the group consisting of nitrous oxide, nitrogen, and carbon dioxide.

18. The system of claim 1 further comprising a temperature sensor for sensing a temperature of the system.

19. The system of claim 1 further comprising an introducer which is insertable into the cooling jacket.

20. The system of claim 1 wherein the cooling jacket is configured in length to match a radiating portion of the microwave antenna.

21. The system of claim 1 wherein the cooling jacket defines at least a first and a second region adjacent to and separate from one another, the first region being adapted to retain the cooling fluid from a first source in fluid contact with a first portion

of the microwave antenna, and the second region being adapted to retain cooling fluid from a second source in fluid contact with a second portion of the microwave antenna.

22. The system of claim 21 wherein the cooling fluid from the first source is maintained at a first temperature and the cooling fluid from the second source is maintained at a second temperature.

23. The system of claim 21 wherein the cooling jacket defines a plurality of additional regions adjacent to and separate from one another.

24. The system of claim 1 wherein the cooling jacket defines at least a first and a second region adjacent to and separate from one another, the first region being adapted to retain the cooling fluid from a first source in fluid contact with a first portion of the microwave antenna, and the second region being adapted to retain cooling fluid from the first source in fluid contact with a second portion of the microwave antenna.

X. EVIDENCE APPENDIX

None

Appl. No. 10/622,800
Brief on Appeal dated April 25, 2007
Reply to Final Office Action mailed October 26, 2006

XI. RELATED PROCEEDINGS APPENDIX

None